

PATENT
674583-2001

REMARKS

Reconsideration and withdrawal of the rejections of the application is respectfully requested in view of the remarks herein.

I. STATUS OF THE CLAIMS AND FORMAL MATTERS

Claims 1-17 are now pending. Claims 1, 2 and 5 are amended herein, without prejudice, without admission, without surrender of subject matter, and without any intention of creating any estoppel as to equivalents.

No new matter is added.

It is submitted that these claims are and were in full compliance with the requirements of 35 U.S.C. §112. In addition, the amendment and remarks herein are not made for the purpose of patentability within the meaning of 35 U.S.C. §§101, 102, 103 or 112; but rather the amendments and remarks herein are made simply for clarification and to round out the scope of protection to which Applicants are entitled. Support for the amended claims is found throughout the specification.

II. THE REJECTIONS UNDER 35 U.S.C. §112 ARE OVERCOME

Claim 1 was rejected under 35 U.S.C. §112, second paragraph as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter of the invention. Specifically, the Office Action alleged that the claim could be interpreted as three separate inventions. Applicants respectfully traverse.

It is respectfully submitted that claim 1 clearly relates to two compositions, the first comprising a coagulation factor IXa and the second comprising a coagulation factor VIII. The two compositions, however, can be administered (1) simultaneously, wherein, e.g., the two compositions are admixed prior to being administered, (2) simultaneously and separately, wherein, e.g., the two compositions are administered at the same time but are not mixed prior to administration, or (3) sequentially, wherein, e.g., the two compositions are each administered with some amount of time passing between the administration of the first and second compositions. Regardless of the actual administration, each recipient would receive both compositions, with the only variable relating to the actual administration of the two compositions. Accordingly, it is respectfully submitted that the claimed invention of two

PATENT
674583-2001

compositions is clear and definite as described in claim 1. Reconsideration and withdrawal of the rejection under 35 U.S.C. §112, second paragraph, is respectfully requested.

Claims 1, 2, 4 and 13 were rejected under 35 U.S.C. §112, second paragraph as being indefinite for the improper use of acronyms. The rejection is respectfully traversed. It is respectfully submitted that the amendments herein have introduced the full names of the coagulation factors into the claims, thereby obviating the rejection. Accordingly, reconsideration and withdrawal of the rejection under 35 U.S.C. §112, second paragraph, is respectfully requested.

Claim 2 was rejected under 35 U.S.C. §112, second paragraph, as allegedly lacking the required steps of the process claimed. The rejection is respectfully traversed. It is respectfully submitted that the amendment herein has introduced the required step into the claim, such that the rejection is moot. Accordingly, reconsideration and withdrawal of the rejection under 35 U.S.C. §112, second paragraph, is respectfully requested.

Claim 13 was rejected under 35 U.S.C. §112, second paragraph, as being indefinite for reciting the term "potentiating". It is respectfully submitted that "potentiating" is a term of art that would be understood by one of skill in the art and would not cause any confusion or be considered indefinite. Further, it is well settled that if the meaning of a term is in dispute, which Applicants respectfully submit is not the situation with the term "potentiating", a dictionary may be consulted to determine the appropriate definition.

Attached hereto are copies of definitions of "potentiating" from Dictionary.com and Answers.com, both of which include as a definition "to promote or strengthen". And, more specifically, both references specify that the "promot[ing] or strength[ening]" can be of "a biochemical or physiological action or effect." Accordingly, it is respectfully submitted that one of skill in the art would interpret the term "potentiating" in claim 13 as meaning that the biochemical or physiological action or effect of FVIII was promoted or strengthened as a result of the step of mixing together factor VIII and factor IXa into a composition. Consequently, reconsideration and withdrawal of the rejection of claim 13 under 35 U.S.C. §112, second paragraph, is respectfully requested.

PATENT
674583-2001

III. THE OBJECTIONS TO THE SPECIFICATION AND CLAIMS ARE OVERCOME

Claims 1 and 5 were objected to as allegedly improperly using the word "which". And, the title of the application was objected to as the title "Composition" allegedly does not reflect the nature of the invention. The objections are respectfully traversed. It is respectfully submitted that the Amendment herein obviates the objections. Accordingly, reconsideration and withdrawal of the objections of the application and claims are respectfully requested.

IV. THE REJECTIONS UNDER 35 U.S.C. §101 ARE OVERCOME

Claim 2 was rejected under 35 U.S.C. §101 as reciting an improper process claim. The rejection is respectfully traversed. It is respectfully submitted that the amendment herein has added a required step to the claim, such that the rejection is now moot. Accordingly, reconsideration and withdrawal of the rejection under 35 U.S.C. §101 is respectfully requested.

V. THE ART REJECTIONS ARE OVERCOME

Claims 1-3 were rejected under 35 U.S.C. §102(b) as allegedly being anticipated by Horikoshi et al. (U.S. 4,348,384). Claims 1, 4-8, and 13-15 were rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Horikoshi et al. The rejections are respectfully traversed and will be addressed in turn.

Initially, it is respectfully submitted that for a Section 102 rejection to stand, the single prior art reference must contain all of the elements of the claimed invention, *see Lewmar Marine Inc. v. Barient Inc.*, 3 U.S.P.Q.2d 1766 (Fed. Cir. 1987), and, the single prior art reference must contain an enabling disclosure, *see Chester v. Miller*, 15 U.S.P.Q.2d 1333, 1336 (Fed. Cir. 1990).

The Office Action alleges that US 4,348,384 describes a pharmaceutical composition comprising effective amounts of coagulation factor VIII or factor IX. It is respectfully submitted that U.S. 4,348,843 does not anticipate the present claims because the present invention does not relate to a pharmaceutical composition comprising effective amounts of coagulation factor VIII or factor IX. Rather, the present invention relates to two pharmaceutical compositions, one containing coagulation factor IXa, the other containing coagulation factor VIII, which may be administered simultaneously, simultaneously and separately, or sequentially. Therefore, U.S. 4,348,384 does not anticipate the present claims as it does not contain all of the elements of the

PATENT
674583-2001

present invention. U.S. 4,348,384 involves factors IX and VIII, not IXa and VIII as in the present invention. Simply, factor IX is not the same as factor IXa.

Factor IX is a single-chain plasma glycoprotein (MW 57,000) that participates in the middle phase of the intrinsic pathway of blood coagulation. Factor IX is present in plasma as a zymogen and is converted to a serine protease, factor IXa, by factor XIa (activated plasma thromboplastin antecedent) in the presence of calcium ions. In the activation reaction, two internal peptide bonds are hydrolyzed in factor IX, resulting in the generation of factor IXa (MW 46,000). To demonstrate the differences between factors IX and IXa, enclosed is a paper by Scipio *et al.* explaining the activation of factor IX to factor IXa (see the Abstract). Additionally, the activation of factor IX to factor IXa is also described at pages 10-12 of the specification as filed.

Accordingly, claims 1-3 are novel because US 4,348,384 does not disclose a composition comprising factor VIII and a composition comprising factor IXa for simultaneous, simultaneous separate or sequential use for treating haemophilia A or B. Indeed, U.S. 4,348,384, as discussed, does not describe the use of factor IXa anywhere in the patent. Therefore, as U.S. 4,348,384 does not contain all of the elements of the present claims, the rejection must be withdrawn.

Furthermore, even if U.S. 4,348,384 were to discuss factor IXa, the present claims could still be distinguished from US 4,348,384 because the document teaches the use of factor VIII or factor IX (for example, see the Abstract and claim I), whereas the claims of the present application relate to factor VIII and factor IXa for the treatment of haemophilia A or B.

Therefore, reconsideration and withdrawal of the rejection under 35 U.S.C. §102(b) is respectfully requested.

Turning now to the Section 103 rejection, the Examiner is respectfully reminded that for a Section 103 rejection, there must be some prior art teaching which would have provided the necessary incentive or motivation for modifying the reference teachings to arrive at the claimed invention. *In re Laskowski*, 12 U.S.P.Q. 2d 1397, 1399 (Fed. Cir. 1989); *In re Obukowitz*, 27 U.S.P.Q. 2d 1063 (BOPAI 1993). Further, the Examiner is respectfully reminded that "obvious to try" is not the standard under 35 U.S.C. §103. *In re Fine*, 5 U.S.P.Q. 2d 1596, 1599 (Fed. Cir. 1988). And, as stated by the Court in *In re Fritch*, 23 U.S.P.Q. 2d 1780, 1783-1784 (Fed. Cir. 1992): "The mere fact that the prior art may be modified in the manner suggested by the Examiner does not make the modification obvious unless the prior art suggests the desirability of

PATENT
674583-2001

the modification.” Also, the Examiner is additionally respectfully reminded that for the Section 103 rejection to be proper, **both the suggestion of the claimed invention and the expectation of success must be founded in the prior art, and not Applicants’ disclosure.** *In re Dow*, 5 U.S.P.Q.2d 1529, 1531 (Fed. Cir. 1988).

Furthermore, the Examiner is also respectfully reminded that MPEP 2143.01 mandates that for a Section 103 rejection, there must be some suggestion or motivation to modify reference teachings, and, that MPEP 2143.02 further mandates that for a Section 103 rejection, there must be a reasonable expectation of success.

Thus, both the case law and the MPEP require that for a Section 103 rejection, there must be some teachings, suggestion, motivation, or incentive to modify reference teachings to arrive at the claimed invention, and there must be some reasonable expectation of success of the claimed invention.

The Office Action alleges that claims 1, 4-8 and 13-15 are unpatentable over U.S. 4,348,384 because it would have been obvious for a person of ordinary skill in the art to combine a composition of coagulation factor IX with a second composition of factor VIII since the compounds are used separately in the treatment of haemophilia A or B. Applicants respectfully disagree.

As described above, U.S. 4,348,384 is not relevant to the present application because there is no mention of a composition comprising factor VIII and a composition comprising factor IXa for simultaneous, simultaneous separate or sequential use for treating haemophilia A or B. Indeed, as described above, US 4,348,384 does not even mention coagulation factor IXa. Rather, US 4,348,384 is concerned with factor IX, a factor that is not present in the claims of the present invention.

Furthermore, even if U.S. 4,348,384 was related to factor IXa, which it indeed is not, the present invention would still be patentable over U.S. 4,348,384 as a skilled person would have not have expected that factor IXa allows the concentration of factor VIII in a composition for the treatment of haemophilia A or haemophilia B to be reduced when compared to a composition which does not comprise factor IXa. This ability to reduce the concentration of factor VIII when given with factor IXa is a surprising result that renders the present application patentable.

Accordingly, reconsideration and withdrawal of the rejections under 35 U.S.C. §103(a) are respectfully requested.

PATENT
674583-2001**REQUEST FOR INTERVIEW**

If any issue remains as an impediment to allowance, prior to issuance of any paper other than a Notice of Allowance, an interview with the Examiner is respectfully requested, and the Examiner is respectfully requested to contact the undersigned to arrange a mutually convenient time and manner for such an interview.

CONCLUSION

In view of the amendments and remarks herewith, the application is in condition for allowance. Favorable reconsideration of the application and prompt issuance of a Notice of Allowance are earnestly solicited.

Respectfully submitted,
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